UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,354	11/07/2001	Julio C. Spinelli	279.373US1	4381

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EXAMINER
GREENE, DANA D

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)
	10/008,354	SPINELLI ET AL.
	Examiner	Art Unit
	Dana D. Greene	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **3** MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *9/1/05*.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____ .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 10-19, 24-27, 30-42, and 46 stand rejected under 35 U.S.C. §102(e)

as being anticipated by Nichols et al. (US 6,363,282 B1, hereinafter "Nichols"). Nichols

is considered to disclose:

a network (*see* col. 1, ln. 10-16 and col. 3, ln. 45-65, Nichols). The disclosed

network is considered to anticipate the claimed network because both provide a network

interface for communicating with a medical device programmer over a network and a

prescription system coupled to the network interface;

a central server coupled to the network and including at least one prescription

system for prescribing at least one programmable parameter of a medical device based

upon at least one characteristic of a patient (*see* col. 6, ln. 60 – col. 7, ln. 10 & col. 9, ln.

20-30, Nichols). The disclosed server configuration is considered to anticipate the

claimed central server because both are capable of receiving a characteristic of a

patient and configured with a processor for receiving at least one prescribed parameter

of the medical device from the central server via the network, and programs the medical

device using the at least one prescribed parameter via the medical device interface;

a medical device programmer coupled to the network and configured to

communicate at least one characteristic of a patient to the central server via the

network, to receive at least one programmable parameter from the central server via the

network, and to program the medical device using the at least one programmable

parameter (see col. 6, ln. 61- col. 7, ln. 55, Nichols). The disclosed programmer is

considered to anticipate the claimed programmer because both supply at least one

patient characteristic to the central server via the network and the at least one

prescribed programmable parameter is then transmitted back to that programmer via

network 102 for use in programming a medical device that will provide therapy for the

patient.

Referring to claims 2, 16, 26, and 40, Nichols is considered to disclose a wide

area network (see col. 6, ln. 38-60, Nichols). The disclosed network is considered to

anticipate the claimed WAN because both allow for bidirectional communications to

occur over a wide geographic area. In this connection, the use of a wide area network

reduces any geographic restrictions placed on the locations of central server, medical

device programmer(s), and expert client(s), and any two of these components can be

physically located close to one another, far from one another, or any distance in

between.

With reference to claims 3-5, 17-19, 27, and 41-41, Nichols is considered to

disclose an expert prescription system defined by an expert to prescribe at least one

parameter of a medical device based on patient characteristics (see col. 6, ln. 60 – col.

7, ln. 10, Nichols). The disclosed expert system is considered to anticipate the claimed

expert prescription system because both work to determine a set of parameters for use

in programming an implantable medical device.

Referring to claims 10, 24, 30, and 46, Nichols is considered to disclose a

medical device programmer configured to program an implantable medical device (see

col. 6, ln. 1-10, Nichols). The disclosed device is considered to anticipate the claimed

device because both are configured for parameters to be updated by the programmer,

which provides bidirectional telemetry between the programmer and the implantable

device.

With reference to claims 11-14, 31-34, and 36-39, Nichols is considered to teach

an interface to receive signals from at least one user input device that represent at least

one of the at least one characteristic of the patient (see col. 9, ln. 55 – col. 10, ln. 20,

Nichols). The disclosed device contains sense amplifiers for detecting cardiac signals

that represent patient activity and other physiologic sensors for sensing the need for

cardiac output. The disclosed interface is considered to anticipate the claimed interface

because both receive and process signals from the input device.

With reference to claim 15, Nichols is considered to disclose:

a network interface for communicating with a medical device programmer over a

network (see col. 8, ln. 60-67, Nichols). The disclosed interface is considered to

anticipate the claimed interface because enable communication of at least one

characteristic of a patient to the central server via the network, receives at least one

programmable parameter from the central server via the network, and programs the

medical device using the at least one programmable parameter;

at least one prescription system coupled to the network interface, each

configured to receive at least one characteristic of a patient from the medical device

programmer via the network, to prescribe at least one programmable parameter of a

medical device based on the at least one characteristic of the patient, and to transmit

the at least one prescribed programmable parameter to the medical device programmer

via the network (see col. 6, ln. 60 – col. 7, ln. 10 & col. 9, ln. 20-30, Nichols). The

disclosed configuration is considered to anticipate the claimed system because both are

capable of receiving a characteristic of a patient and configured with a processor for

receiving at least one prescribed parameter of the medical device from the central

server via the network, and programs the medical device using the at least one

prescribed parameter via the medical device interface;

Referring to claim 25, Nichols is considered to disclose:

a network interface for communicating over a network with at least one

prescription system residing on a central server (see col. 2, ln. 64 – col. 3, ln. 12,

Nichols). The disclosed drug delivery system is considered to anticipate the claimed

prescription system because both prescribe at least one parameter of an implantable

medical device based on at least one characteristic of a patient over a network;

a medical device interface for communicating with a medical device (see col. 8,

ln. 60-67, Nichols). The disclosed programmer and web-top unit are considered to

anticipate the claimed medical device interface because both enable communication with the medical device;

a processor coupled to the network interface and the medical device interface, and configured to communicate at least one characteristic of a patient to the central server via the network, to receive at least one prescribed programmable parameter of the medical device from the central server via the network, and to program the medical device using the at least one prescribed programmable parameter via the medical device interface (*see* col. 14, ln. 39 – 60, Nichols). The disclosed processor is considered to anticipate the claimed processor because both are connected and interfaced with a network and store and retrieve programmable parameters for the medical device and transfer certain physiological parameters to the central server via the network.

With reference to claim 35, Nichols is considered to disclose:

determining at least one characteristic of a patient at a programmer (*see* col. 1, ln. 5-20, Nichols). Nichols teaches utilizing various types of networks platforms to perform patient diagnosis on the programmer;

communicating the at least one characteristic to a central server (*see* col. 1, ln. 5-20, Nichols). Nichols teaches a remote bi-directional communications with one or more devices that are associated with IMDs and communications between a web-based data center and a programmer;

determining at least one programmable parameter for a medical device based on the at least one characteristic using a prescription system hosted by the central server;

communicating the at least one programmable parameter to the programmer; and

programming the medical device using the at least one programmable parameter (*see*

col. 8, ln. 50-60, Nichols). The disclosed method of determining parameters is

considered to anticipate the claimed method because both are implemented when

programming commands are transmitted from the programmer to the implantable

medical device;

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-9, 20-23, 28, 29, and 43-45 stand rejected under 35 U.S.C. §103(a) as

being unpatentable over Nichols in view of Haller (US 6,804,558 B2, hereinafter

"Haller"). Nichols is considered to disclose the claimed invention as discussed above,

under the anticipatory rejection, except for the claimed custom prescription system.

However, Haller is considered to disclose the claimed custom prescription system (see

col. 45, ln. 26-29, Haller). It would have been obvious to one having ordinary skill in the

art to combine the teachings of Nicholas with Haller's teaching of a remote expert

computer system capable of determining on the basis of analysis whether the patient

requires further attention, correction, or intervention (see col. 45, ln. 26-29, Haller). In

this connection, Haller also discloses a prescription table particular to a patient that is

stored in the implantable medical device, communication module, and/or remote system

that may be quickly and readily read (see col. 46, ln. 40-45, Haller). It would have been obvious to one of ordinary skill in the art to combine the teachings of Nichols with the prescription system and expert computer system found in Haller for the purpose of the centralized management system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
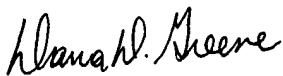
Dana D. Greene
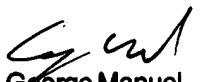
George Manuel
Primary Examiner